K083843

MAR 2 0 2009

SECTION 5 – 510(K) SUMMARY

Submitted by:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581 Phone: (305) 269-6386 Fax: (305) 269-6441
Contact Person:	Suzana Otaño, Project Manager, Regulatory Affairs
Date Prepared:	December 23, 2008
Proprietary Name:	Locking Anatomic & Composite Plating System
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030)
Predicate Devices:	The DePuy Locking Anatomic & Composite Plating System is substantially equivalent to currently marketed devices.
Intended Use:	The DePuy Locking Anatomic & Composite Plating System is intended for fixation of fractures, osteotomies and non-unions of the fibula, malleolus, metatarsals and metacarpals, olecranon, clavicle, scapula, distal humerus and humeral head, radius, ulna and distal tibia, particularly in osteopenic bone.
Technological Characteristics:	The technological characteristics of the DePuy Locking Anatomic & Composite Plating System are similar to the predicate devices including design and material.
Summary of Substantial Equivalence:	The DePuy Locking Anatomic & Composite Plating System is substantially equivalent to currently marketed devices as demonstrated with pre-clinical data. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2009

DePuy Orthopaedics, Inc.
% Ms. Suzana Otaño
Project Manager, Regulatory Affairs
700 Orthopaedic Dr.
Warsaw, Indiana 46581-0988

Re: K083843
Trade/Device Name: Locking Anatomic & Composite Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: December 23, 2008
Received: December 24, 2008

Dear Ms. Otaño:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K083843

Device Name: **Locking Anatomic & Composite Plating System**

Indications For Use:

The DePuy Locking Anatomic & Composite Plating System is intended for fixation of fractures, osteotomies and non-unions of the fibula, malleolus, metatarsals and metacarpals, olecranon, clavicle, scapula, distal humerus and humeral head, radius, ulna and distal tibia, particularly in osteopenic bone.

Prescription Use X AND/OR Over-the-Counter
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083843